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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/518,462	12/22/2004	Yu Nagase	584282000100	4995

25227 7590 09/25/2007

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EXAMINER	
SHIAO, REI TSANG	
ART UNIT	**PAPER NUMBER**
1626	

MAIL DATE	DELIVERY MODE
09/25/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/518,462	NAGASE ET AL.	
	Examiner	Art Unit	
	Rei-tsang Shiao, Ph.D.	1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 August 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8* is/are pending in the application.

4a) Of the above claim(s) *5-8* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *22 December 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/22/04, 03/11/05, 1/12/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This application claims benefit of the foreign applications:

JAPAN 2003-040154 with a filing date 02/18/2003.

2. Claims 1-8 are pending in the application.

Information Disclosure Statement

3. Applicant's Information Disclosure Statements, filed on December 22, 2004, March 11, 2005, and January 12, 2007 have been considered. Please refer to Applicant's copies of the 1449's submitted herein.

Responses to Election/Restriction

4. Applicant's election with traverse of election of Group I claims 1-4, in the reply filed on August 08, 2007 is acknowledged. The traversal is on the grounds that the Examiner fails to explain the requirement properly, in a way that applicants can respond to it properly, means that the requirement must be restated or withdrawn, and MPEP 1850 is cited. This is found not persuasive, and the reasons are given *infra*.

Claims 1-8 are pending in the application. The scope of the invention of the elected subject matter is as follows.

Claims 1-4 are drawn to compounds of the formula (I).

The claims 1-8 herein lack unity of invention under PCT rule 13.1 and 13.2 since the compounds defined in the claims lack a significant structural element qualifying as the special technical feature that defines a contribution over the prior art,

see Arimori et al. US 6,040,415 or Straford et al. US 5,591,882. Arimori et al. or Straford et al. discloses similar phosphorylcholine compounds/ploymer of formula (I) as the instant invention. Accordingly, unity of invention is considered to be lacking and restriction of the invention in accordance with the rules of unity of invention is considered to be proper. Furthermore, even if unity of invention under 37 CFR 1.475(a) is not lacking, which it is lacking, under 37 CFR 1.475(b) a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations:

> (1) A product and a process specially adapted for the manufacture of said product', or
>
> (2) A product and a process of use of said product; or
>
> (3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or
>
> (4) A process and an apparatus or means specifically designed for carrying out the said process; or
>
> (5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process.

And, according to 37 CFR 1.475(c)

> if an application contains claims to more or less than one of the combinations of categories of invention set forth in paragraph (b), unity of invention might not be present.

However, it is noted that unity of invention is considered lacking under 37 CFR 1.475(a) and (b). Therefore, since the claims are drawn to more than a product, and according to 37 CFR 1.475 (e)

> the determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claim.

The claims lack unity of invention and should be limited to only a product, or a

process for the preparation, or a use of the said product. In the instant case, Groups I-II are drawn to various products, and the products of compounds of formula (I) (i.e., claims 1-4) do not contain a common technical feature or structure of claims 5-8 (i.e., polymer), and do not define a contribution over the prior art, i.e., phosphorylcholine compounds of Arimori et al. or Straford et al. Moreover, the examiner must perform a commercial database search on the subject matter of each group in addition to a paper search, which is quite burdensome to the examiner. Claims 1–4 are prosecuted in the case. Claims 5-8 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention.

The requirement is still deemed proper.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in Graham v. John Deere Co., 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.

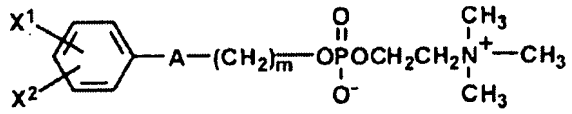
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

5.1 Claims 1-4 are rejected under 35 U.S.C. 103(a) as being obvious over Arimori et al. US 6,040,415.

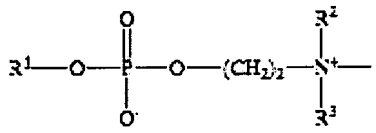
Applicant claim biocompatible phosphorycholine compounds of formula (I), i.e.,



, see claim 1. Dependent claims 2-4 further limit a number of variable, i.e., R1 is hydrogen.

Determination of the scope and content of the prior art (MPEP §2141.01)

Arimori et al. disclose biocompatible phosphorycholine compounds of formula (I), i.e.,



, wherein the variable R^2 or R^3 independently represent C_{1-20} alkyl (i.e., methyl), and the variable R^1 represents C_{7-20} aralkyl (e.g., benzyl, phenylbutyl), see column 7 and 27-28.

Determination of the difference between the prior art and the claims (MPEP §2141.02)

The difference between the instant claims and Arimori et al. is that the instant variable A represents a single bond, -O-, or -COO-, while Arimori et al. represents a single bond at the same position. Arimori et al. compounds are analogous compounds of the instant invention.

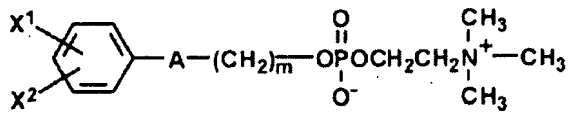
Finding of prima facie obviousness-rational and motivation (MPEP §2142-2143)

One having ordinary skill in the art would find the instant claims 1-4 prima facie obvious **because** one would be motivated to employ the analogous compounds of Arimori et al. to obtain the instant compounds of formula (I), wherein the variable A represents a single bond, and the variable m is an integer of 1 or 4. Dependent claims 2-4 are also rejected along with claim 1 under 35 U.S.C. 103(a).

The motivation to obtain the claimed compounds derives from known Arimori et al. pharmaceutically useful compounds would possess similar activities (i.e., agents of biocompatible compounds) to that which is claimed in the reference.

5.2 Claims 1-4 are rejected under 35 U.S.C. 103(a) as being obvious over Straford et al. US 5,591,882.

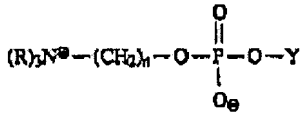
Applicant claim biocompatible phosphorycholine compounds of formula (I), i.e.,

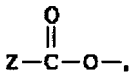


, see claim 1. Dependent claims 2-4 further limit a number of variable, i.e., R1 is hydrogen.

Determination of the scope and content of the prior art (MPEP §2141.01)

Straford et al. disclose biocompatible phosphorycholine compounds of formula (I), i.e.,



, wherein the variable R independently represent C_{1-4} alkyl (i.e., methyl), and the variable n is 0 to 5, the variable Y represents $-(CH_2)a\text{-}Ar\text{-}(CH_2)bX$, and the variable a is 1-5, the variable AR represents phenyl substituted with amino, and the variable b is 0 and the variable X represents  and the variable Z is C_{1-4} alkyl , see column 1-3.

Determination of the difference between the prior art and the claims (MPEP §2141.02)

The difference between the instant claims and Straford et al. is that the instant variable A represents a single bond, -O-, or -COO-, while Straford et al. represents a single bond at the same position. Straford et al. compounds are analogous compounds of the instant invention.

Finding of prima facie obviousness-rational and motivation (MPEP §2142-2143)

One having ordinary skill in the art would find the instant claims 1-4 prima facie obvious **because** one would be motivated to employ the analogous compounds of Straford et al. to obtain the instant compounds of formula (I), wherein the variable A represents a single bond, and the variable m is an integer of 1 or 4. Dependent claims 2-4 are also rejected along with claim 1 under 35 U.S.C. 103(a).

The motivation to obtain the claimed compounds derives from known Straford et al. pharmaceutically useful compounds would possess similar activities (i.e., agents of biocompatible compounds) to that which is claimed in the reference.

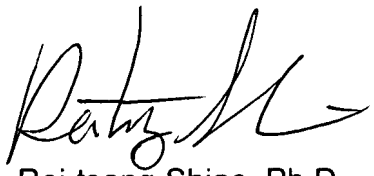
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rei-tsang Shiao whose telephone number is (571) 272-0707. The examiner can normally be reached on 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane can be reached on (571) 272-0699. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Rei-tsang Shiao, Ph.D.
Patent Examiner
Art Unit 1626

September 19, 2007